a massaging and rubbing oil and could be used and rubbed on the body freely without fear of irritation of any kind; that it would be an efficacious treatment for stiff joints; that it would be efficacious in the cure, mitigation, treatment, and prevention of colds, influenza, coughs, asthma, sinus, and catarrhal conditions; that it would be efficacious in the mitigation and treatment of disease and disease conditions accompanied by fever; and that it would be efficacious in dissipating fever and restoring normal body temperature. The article would not be safe for use on every part of the body; it would not be appropriate for use generally as a massaging and rubbing oil, and it might cause irritation to the skin when used as directed; and it would not be efficacious for the purposes represented.

Further misbranding, Section 502 (j), the article was dangerous to health when used in the dosage suggested in the labeling, "Eucalyptus Oil * * * Used in * * * Ear Oil" and "It may be used safely on any part of the body," since when used in the ears the article would cause injury.

Further misbranding, Section 502 (f) (2), the labeling of the article failed to bear such adequate warnings against use in those pathological conditions where its use may be dangerous to health, against unsafe methods and duration of application, in such manner and form, as are necessary for the protection of users, since its labeling failed to bear warnings against allowing the article to get into the eyes and ears or onto the mucous membrane, and against continued use of the article if excessive irritation should develop, since the article might be harmful to the eyes, ears, mucous membrane, and irritated skin.

Further misbranding, Section 505, the article was a new drug within the meaning of the law in that it was not generally recognized, among experts qualified by scientific training and experience to evaluate the safety of drugs, as safe for use under the conditions recommended and suggested in their labeling; and application filed, pursuant to the law, was not effective with respect to the article.

The indictment alleged also that another product, *Sol-A-Min*, was adulterated and misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods.

DISPOSITION: March 31, 1947. The defendant's motion to dismiss the indictment having been denied, a plea of guilty was entered and the court imposed a fine of $1,000, plus costs.

2152. Adulteration and misbranding of procaine hydrochloride solution. U. S. v. A. Pfingst, a partnership, and Ernest Pfingst. Pleas of guilty. Fine of $500 against both defendants jointly and severally. (F. D. C. No. 14300. Sample Nos. 35041–F, 50281–F.)

INFORMATION FILED: March 7, 1947, Southern District of New York, against A. Pfingst, a partnership, and Ernest Pfingst, New York, N. Y.

ALLEGED SHIPMENT: Between the approximate dates of March 7 and 20, 1944, from the State of New York into the States of Georgia and Pennsylvania.

LABEL, IN PART: "Procaine Hydrochloride Solution 2% with Epinephrin (Pfingst)."

NATURE OF CHARGE: Adulteration, Section 501 (c), the purity and quality of the article fell below that which it purported and was represented to possess, since the appropriate use for the article required that it be a sterile product, whereas it was nonsterile and contaminated with living micro-organisms.

Misbranding, Section 502 (j), the article would be dangerous to health when used in the dosage suggested in the labeling, due to the presence of living micro-organisms.

DISPOSITION: May 1, 1947. Pleas of guilty having been entered, the court imposed a fine of $500 against both defendants jointly and severally.

2153. Misbranding of first aid kits and contents. U. S. v. 15,000, etc. (F. D. C. Nos. 20530, 20531. Sample Nos. 63802–H to 63804–H, incl.)

LIBELS FILED: July 18, 1946, Southern District of New York.

ALLEGED SHIPMENT: Between the approximate dates of May 17 and August 13, 1945, by Burke Drug Supply, from Dayton, Ohio.

PRODUCT: 15,000 complete *first aid kits with contents* and 5,500 *incomplete first aid kits* at New York, N. Y.; also 5,500 vials of *Amphetamine sulfate tablets*, 5,500 vials of *wound tablets*, and 500 vials of *atabrine tablets*, all of which had

been removed from the incomplete kits. These kits contained a bottle of *mild tincture of iodine.* The kits were intended to be incorporated into certain emergency equipment for utilization by the Army.

LABEL, IN PART: (First aid kits) "First Aid Instructions Vest, Emergency, Sustenance Type C-1."

NATURE OF CHARGE: *Amphetamine sulfate tablets*, misbranding, Section 502 (j), the article would be dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, and suggested in the labeling, as follows: (case and vial label) "Directions: Take one tablet if sleepy or two tablets if extremely fatigued. Repeat this dose in six hours if necessary but do not take more than * * * " (vial label) " * * * six tablets in any one week" and (case label) " * * * four tablets in any 12 hour period."

Wound tablets, misbranding, Section 502 (j), the article would be dangerous to health when used in the dosage prescribed, recommended, and suggested in the labeling, as follows: (vial label) "Use—When Hit: Take all tablets. Drink lots of water" and (case label) "Wounds—Take internally by mouth, followed by a large amount of water, 8 Sulfadiazine Tablets."

Atabrine tablets, misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use, since the following directions appearing in the labeling were not adequate directions for use in the prevention or treatment of malaria: (vial label) "Use: For prevention of Symptoms of Malaria. Take first dose (1 tablet) in the morning and second dose (1 tablet) in the evening after meals on two days of each week. Skip 2 or 3 days between days of taking Atabrine. Start to take Atabrine on first day you are in malarial area and continue to take it as long as you are in a malarial area" and (case label) "Malaria (Chills and Fever) (Prevention) * * * ." [Directions similar to those on vial.]

Mild tincture of iodine, misbranding, Section 502 (a), the statement "50% isopropyl alcohol" on the label was false and misleading since the article contained no isopropyl alcohol.

DISPOSITION: On November 20, 1946, the Ever Ready First Aid Company, New York, N. Y., claimant for the products, with the exception of 2,500 complete first aid kits, having admitted the allegations of the libel, judgment of condemnation was entered and it was ordered that the products be released under bond to be relabeled and repackaged as specified in the order, so as to comply with the law, under the supervision of the Food and Drug Administration. On November 6, 1946, the claim for the 2,500 remaining kits having been withdrawn, judgment of condemnation was entered and the product was ordered delivered to the Department of Hospitals of the City of New York.

2154. Misbranding of first aid kits. U. S. v. 13,500 * * *. (F. D. C. No. 20586. Sample No. 63805-H.)

LIBEL FILED: August 9, 1946, Southern District of New York.

ALLEGED SHIPMENT: Between the approximate dates of May 22 and August 14, 1945, by Burke Drug Supply, from Dayton, Ohio.

PRODUCT: 13,500 complete *first aid kits* at New York, N. Y. These kits were intended for use as part of emergency equipment for the Army. When the war ended, the contract was terminated and the kits were sold separately as surplus to a private dealer. Each of the kits contained, among other items, vials of tablets designated as "Amphetamine Sulfate— 5 MG.," "Atabrine Tablets," and "Wound Tablets," and a small bottle of a solution designated as "Mild Tincture Iodine 2 cc. U.S.P. * * * 50% Isopropyl Alcohol." The *wound tablets* contained sulfadiazine. The *mild tincture iodine* contained no isopropyl alcohol.

LABEL, IN PART: "First Aid Instructions Vest, Emergency, Sustenance Type C-1."

NATURE OF CHARGE: *Mild tincture iodine*, misbranding, Section 502 (a), the label statement "50% Isopropyl Alcohol" was false and misleading since the article contained no isopropyl alcohol.

Atabrine tablets, misbranding, Section 502 (f) (1), the label failed to bear adequate directions for use since the following directions appearing in the labeling were not adequate directions for use in the prevention or treatment of malaria: (Vial label) "Use: for prevention of Symptoms of Malaria. Take